



## ENZYMATIC THERAPY INCORPORATED

What **Better** feels like.™

November 22, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Cleanse* Fiber Formula	Fiber binds to toxins, adds bulk to fecal matter, makes bowel movements easier to pass, and provides a rich source material for beneficial bacteria to form short chain fatty acids – SCFA for short – that are absorbed by the colon to increase fecal matter bulk and to be used as energy.*	Proprietary Fiber Blend – psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/22/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Financial Officer

INTEGRATIVE THERAPEUTICS INC.™  
NF Formulas • PhytoPharmica  
Tyler Encapsulations • Vitamine Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 • F: 503.582.0467

ENZYMATIC THERAPY®  
&  
PHYTOPHARMICA®

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 • F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 • F: 920.469.4418 (Phyto)

0554 5 DEC 12 P2:27

975 0162

LET

17041



## ENZYMATIC THERAPY INCORPORATED

*What **Better** feels like.™*

### INTEGRATIVE THERAPEUTICS INC.™

NF Formulas • PhytoPharmica  
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 • F: 503.582.0467

### ENZYMATIC THERAPY™

&  
**PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 • F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 • F: 920.469.4418 (Phyto)

November 22, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Cleanse* Fiber Formula	Fiber has demonstrated, in numerous clinical studies, support of cardiovascular, immune, and endocrine function health in addition to its gastrointestinal role.*	Proprietary Fiber Blend – psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: 

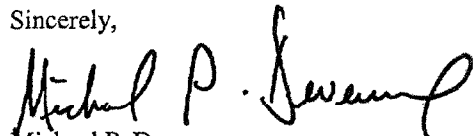
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/22/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer



## ENZYMATIC THERAPY INCORPORATED

*What **Better** feels like.™*

**INTEGRATIVE THERAPEUTICS INC.™**  
NF Formulas ♦ PhytoPharmica  
Tyler Encapsulations ♦ Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 ♦ F: 503.582.0467

**ENZYMATIC THERAPY™  
&  
PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

November 22, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Simple Cleanse* Fiber Formula	The fibers actually swell up when they're exposed to fluids, which helps move waste substances through your body more effectively.*	Proprietary Fiber Blend – psyllium (Plantago ovata) husk, oat (Avena sativa) bran, guar gum (Cyamopsis tetragonoloba) seed extract, pectin (from citrus fruit), marshmallow (Althaea officinalis) root extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: \_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/22/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

Michael P. Devereux  
Chief Financial Officer